urease in the gastrointestinal tract of the mammal, and (2) an inhibitor of gastric acid secretion.

REMARKS

Entry of the foregoing, and prompt and favorable consideration on the merits of all the claims of record in the subject application are respectfully requested.

By the foregoing amendment, claim 1 has been amended to insert the phrase "the adhesion portion of Helicobacter pylori urease." Support for this amendment can be found throughout the originally filed application, including for example page 3, line 3 through page 4, line 8. Thus, no new matter has been added.

Turning now to the Official Action, the Examiner has required restriction amongst the claims. In particular, the Examiner has required restriction amongst the claims as follows:

I. Claims 1-2, drawn to a composition comprising IgY antibodies and an inhibitor of gastric acid secretion;

II. Claims 3-4, drawn to a pharmaceutical composition comprising IgY antibodies, an inhibitor of gastric acid secretion, and a pharmaceutically acceptable carrier;

III. Claim 5, drawn to a method for inhibiting *Helicobacter pylori* adhesion comprising administration of a composition comprising a therapeutically effective amount of IgY antibodies and inhibitor gastric acid secretion; and,

IV. Claim 6, drawn to a method for preventing and/or treating a disease caused by or associated with *Helicobacter pylori* comprising administration of a composition comprising a therapeutically effective amount of IgY antibodies and inhibitor gastric acid secretion.

Applicants elect, with traverse, Group I (claims 1 and 2) directed to a composition comprising IgY antibodies and an inhibitor of gastric acid secretion.

According to Section 803 of the M.P.E.P., a restriction under 35 U.S.C. § 121 is only proper where there is a serious burden on the Examiner to examine all of the claims in a single application. This is true even when appropriate reasons exist for restriction.

It is respectfully submitted that examination of at least Group I (claims 1 and 2) and Group II (claims 3-4 -- directed to a pharmaceutical composition comprising IgY antibodies, an inhibitor of gastric acid secretion, and a pharmaceutically acceptable carrier) together would not place a serious or undue burden on the Examiner. The Examiner attempts to argue that the pharmaceutical composition is unrelated to the composition in general because the "pharmaceutical composition requires not only in vitro but also in-*vivo* study to prove the pharmaceutical efficacy including phamakokinetic [sic] and pharmacodynamic." The Examiner, however, is incorrect in stating that the pharmaceutical composition requires both *in vitro* and *in vivo* studies to prove pharmaceutical efficacy. The Federal Circuit has clearly indicated that *in vivo* test results are no a requirement for obtaining a patent. *See.e.g., In re Brana*, 34 U.S.P.Q. 2d 1437, 1442 (Fed. Cir. 1995). Rather, the Federal Circuit has admonished the United States Patent and Trademark Office for confusing the requirements under the law for obtaining a

patent with the requirements for obtaining approval to market a particular drug for human consumption. *Id.*

Furthermore, it is evident from United States Patent No. 6,419,926 that the examination of claims directed to both the composition in general and a pharmaceutical composition does not create an undue or serious burden on the Examiner.

It is also submitted that the examination of the claims directed to methods of using the composition (Groups III-IV -- claims 5 and 6, respectively) along with the claims directed to the composition (Group I -- claims 1 and 2) would not be a serious or undue burden on the Examiner, particularly since the search for the methods of use would necessarily include a search for the composition.

Therefore, applicants respectfully request that the Examiner reconsider the requirement for restriction and examine all of the claims of record (claims 1-6) together in the same application.

In the event the Examiner maintains the requirement for restriction amongst the claims drawn to the elected composition (claims 1 and 2) and the claims drawn to the process of using the elected composition (claims 5 and 6), the Examiner is reminded that once the composition claims are found allowable then the process claims using the allowable composition shall be rejoined. *See* M.P.E.P. § 821.04.

In the event that there are any questions relating to this Amendment and Reply to Restriction Requirement or the application in general, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of the application may be expedited.

Respectfully submitted,

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Date: October 24, 2002

Attachment to Amendment and Reply to Restriction Requirement dated October 24, 2002

Marked-up Copy of Claim 1

1. (Amended) An inhibitor composition of *Helicobacter pylori* adhesion in the gastrointestinal tract of a mammal including humans, comprising (1) IgY antibodies obtained from at least one chicken egg laid by a hen which has been immunized with an antigenically effective amount of an isolated *Helicobacter pylori* urease, wherein said IgY antibodies are capable of specifically binding to the adhesion portion of *Helicobacter pylori* urease in the gastrointestinal tract of the mammal, and (2) an inhibitor of gastric acid secretion.